

mass spectrometry (SELDI-TOF) indicated that various chips yielded spectra that were inconsistent with one another. Similar effects were observed with respect to spectra obtained using electrospray techniques. This inconsistency can lead to inaccurate results when running a diagnostic.

### SUMMARY OF THE INVENTION

[0006] The present invention provides a QA/QC method for filtering out inconsistencies across high-throughput bioassay processes, particularly across different biochips and different diluents or concentrations of diluents used in electrospray techniques.

[0007] The present invention uses the Knowledge Discovery Engine ("KDE") to identify hidden patterns across a wide variety of serum samples and biochips to generate a control model and agnostic to the underlying disease processes in question. Electrospray, MALDI-TOF (Matrix Assisted Laser Desorption/Ionization-Time of Flight) mass spectra, or SELDI-TOF (Surface Enhanced Laser Desorption/Ionization-Time of Flight) mass spectra can be analyzed in this manner, for example. Alternatively, the invention may use the KDE to identify hidden patterns across a variety of serum to diluent concentrations to generate a control model. In yet another embodiment, the KDE may be used to identify hidden patterns across a variety of diluents and sera samples to generate a control model.

[0008] The KDE is disclosed in U.S. Patent Application Serial No. 09/883,196, now U.S. Patent <sup>7,096,206</sup> Application Publication No. 2002/0046198A1, entitled "Heuristic Methods of Classification," filed June 19, 2001 ("Heuristic Methods"), and U.S. Patent Application Serial No. 09/906,661, now U.S. Patent <sup>6,925,389</sup> Application Publication No. 2003/0004402A1, entitled "A Process for Discriminating Between Biological States Based on Hidden Patterns from Biological Data," filed July 18, 2001 ("Hidden Patterns"); the contents of both applications are hereby incorporated by reference in their entirety. Software running the KDE is available from Correlogic Systems, Inc., under the name Proteome Quest <sup>TM</sup>.

[0009] After the KDE is used to generate a control model, a test serum may be compared to the control model to determine if the spectra produced by the high-throughput bioassay process and the serum are acceptable.